UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
MIDDLE DIVISION
Case No 2:06:04049-CV-NKL

CHRISTINE WINTER, Individually and as Executor of the Estate of RUTH BALDWIN, Deceased,	)
Plaintiff,	)
v.	)
NOVARTIS PHARMACEUTICALS CORPORATION,	)
Defendant.	)

PLAINTIFF'S SUGGESTIONS IN OPPOSITION TO NPC'S MOTION IN LIMINE

Plaintiff Christine Winter ("Plaintiff" or "Ms. Winter"), successor in interest to Ruth Baldwin ("Mrs.. Baldwin"), hereby submits her suggestions in opposition to Novartis Pharmaceutical Company's ("NPC") Motion in Limine and states as follows:

FACTS

In 2001, NPC's patent expired for Aredia, a bisphosphonate (generic name - pamidronate) prescribed by oncologists and other doctors in an attempt to strengthen bones in certain cancer patients. In February 2002, NPC obtained FDA approval to sell Zometa (generic name – zoledronic acid), a more potent bisphosphonate also used to strengthen bones in certain cancer patients. Thereafter, the evidence at trial will show that NPC engaged in a broad based marketing push to encourage oncologists and other doctors to switch from Aredia to Zometa. NPC was widely successful in that Zometa sales quickly exceeded $1billion/year worldwide while Aredia sales were reduced to near zero.

On July 24, 2003, Dr Hueser, an oncologist, prescribed monthly infusions of Aredia, for his patient, the decedent Mrs.. Ruth Baldwin an attempt to reduce the incidence of skeletal-related events ("SREs" i.e. to strengthen her bones). She had metastatic breast cancer. In September 2003, Dr Hueser switched Mrs.. Baldwin from monthly infusions of Aredia to monthly infusions of Zometa.

On November 6, 2003, Dr Miller, a dentist, extracted tooth No 31 in Mrs.. Baldwin's lower right jaw. On September 9, 2004, Dr Miller extracted tooth No 30 in her lower right jaw. It is undisputed that NPC never warned Dr Miller to avoid tooth extractions for patients on Zometa or Aredia prior to September 9, 2004. Instead, NPC claims that it sent Dr. Miller a "dear dentist letter" in May 2005 advising him and other dentists to avoid tooth extractions for patients on Zometa/Aredia and to conduct a full dental exam prior to beginning bisphosphonate therapy.

On October 25, 2004, Dr Miller sent Mrs.. Baldwin to an oral surgeon, Dr Coyle for a consult for her non healing lower right jaw. Dr Coyle agreed to see her the next day, October 26, 2004. Dr Coyle immediately recognized that Mrs. Baldwin had osteonecrosis of the jaw caused by a tooth extraction while on Zometa ("BONJ") and advised Dr Hueser and Dr Miller of that fact and the need to avoid anymore tooth extractions. The undisputed evidence is that Dr Hueser immediately advised Mrs. Baldwin to stop taking Zometa. The medical records show that her last dose was October 21, 2004, 5 days before she saw Dr Coyle. Dr Hueser never asked Mrs. Baldwin to go back on either Zometa or Aredia at anytime before she passed away in November 2006.

PLAINTIFF'S CLAIMS

Plaintiff has asserted claims for strict liability failure to warn, negligent failure to warn and breach of implied warranty of merchantability. In essence, all three claims revolve around

NPC's failure to provide an adequate warning of the danger of BONJ associated with the use of Zometa and Aredia. The central difference between a negligent failure to warn claim and a strict liability failure to warn claim is that a negligent failure to warn claim focuses on whether the manufacturer knew or should have known of certain dangers and whether it adequately warned the consumer of any such dangers while a strict liability failure to warn claim focuses on whether the product was unreasonably dangerous to the consumer without an adequate warning of certain dangers. *Moore v. Ford Motor Co*, 332 S.W.3d 749 (Mo. 2011). Under Missouri law, there is a distinction between instructions and warnings. Warnings signal danger while instructions serve principally to provide the user with information necessary to make proper and efficient use of the product. *Nesselrode v. Executive Beechcraft, Inc*., 707 S.W.2d 371, 385 (Mo. 1986).

As "[t]he manufacturer of a prescription drug to be administered to human beings", Novartis is held to the skill of an expert in that particular business' and `to an expert's knowledge of the arts, materials and processes,' and is bound to keep reasonably abreast of scientific knowledge and discoveries concerning his field and, of course, is deemed to possess whatever knowledge is thereby imparted." *Krug v. Sterling Drug, Inc.,* 416 S.W.2d l43, 152 (Mo. 1967). Novartis had a continuing duty to warn of dangers of which an expert in the pharmaceutical industry knew or should have known, not just what a reasonable person knew or should have known. A product may be rendered unreasonably dangerous because of the absence of a warning concerning its use or misuse, or because the warning that has been given is informationally deficient or inadequate. *Nesselrode v. Executive Beechcraft, Inc*., 707 S.W.2d 371, 382 (Mo. 1986). The imposition of strict tort liability is justified on the grounds that the manufacturer or seller is almost always better equipped than the consumer to endure the economic consequences of accidents caused by unreasonably dangerous products. *Nesselrode,* 707 S.W.2d at 383.

CAUSATION

Under Missouri law, there is a presumption that had an adequate warning been given, it would have been heeded. *Moore v. Ford Motor Co*., 332 S.W.3d 749 (Mo., 2011). Moreover, there is no duty for Plaintiff to provide the exact wording of an adequate warning. He or she must merely prove that the warning provided by the defendant was inadequate. *Moore v. Ford Motor Co*., 332 S.W.3d 749 (Mo. 2011) The proximate cause of an event or injury need only be a substantial factor in causing Plaintiff's injuries, not the only cause of Plaintiff's injuries. *Nesselrode,* 707 S.W.2d at 383.

PUNITIVE DAMAGES

"In a negligence case, punitive damages are awardable only if, at the time of the negligent act, the defendant knew or had reason to know that there was a high degree of probability that the action would result in injury." *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748 (Mo App. 2008), *citing Lewis v. FAG Bearings Corp*., 5 S.W.3d 579, 583 (Mo.App. S.D.1999). Punitive damages are properly submitted in a strict liability case where clear and convincing evidence is presented that defendants "`placed in commerce an unreasonably dangerous product with actual knowledge of the product's defect.'" Peters, 200 S.W.3d at 24 (quoting *Letz v. Turbomeca Engine Corp*., 975 S.W.2d 155, 164-65 (Mo.App. W.D. 1997)). Both strict liability and negligence theories require evidence to be presented that "`the defendant showed a complete indifference to or conscious disregard for the safety of others.'" Id. (citation omitted). "`Conscious disregard or complete indifference' includes situations where the person doing the act or failing to act must be conscious from the knowledge of surrounding circumstances and existing conditions, that, although lacking specific intent to injure, the person's conduct or failure to act will naturally or probably result in injury." Id. The jury may find that the mere fact an

injury occurred indicates a high degree of probability of injury. Kaplan v. U.S. Bank, N.A., 166 S.W.3d 60, 73 (Mo.App. E.D.2003).

NPC'S DEFENSES

Novartis has defended this action and a host of other similar actions in this mdl on a number of common basis including asserting that:

1. NPC was not negligent in failing to warn of the risk of BONJ associated with the use of Zometa/Aredia and the need to avoid dental extractions while on Zometa/Aredia, because it neither knew or should have known of the risk of BONJ (under a negligent failure to warn standard);

2. NPC's failure to warn Mrs.. Baldwin (the ultimate user), her dentist (Dr Miller) or her Oncologist (Dr Hueser) at any time before her September 9, 2004 extraction, of the risk of BONJ when using Zometa/Aredia, especially when undergoing a tooth extraction while on the drug, did not render Zometa/Aredia "unreasonable dangerous" (under a strict liability failure to warn standard);

3. NPC's failure to warn was not a proximate cause of Mrs. Baldwin's BONJ. Specifically, NPC challenges general causation (arguing that Zometa and Aredia generally does not cause BRONJ) and specific causation (arguing that Mrs. Baldwin did not have BONJ and/or that NPC's failure to warn was not a proximate cause of Mrs. Baldwin's BONJ).

ARGUMENT

Much of the evidence sought to be admitted by Mrs. Baldwin - and excluded by NPC - is relevant to Mrs.. Baldwin's failure to warn claims under FRE 401 and 402 and should not be excluded under FRE 403 and is therefore admissible. Moreover, much of Plaintiff's evidence comes from NPC emails and internal documents. That evidence is generally admissible as non

hearsay because it is being offered to show notice to NPC and/or as admissions of a party opponent under FRE 801(d)(2). For instance, evidence of what NPC knew or should have known prior to July 2003 (when Mrs. Baldwin started Aredia) and after September 9, 2004 (when Dr Miller performed his second extraction while she was on Zometa) or after late October 2005 (when she was diagnosed with BONJ), is relevant to the issues of NPC's negligence, general and specific causation, and whether Zometa/Aredia was unreasonably dangerous due to the absence of an adequate warning re: the dangers of BONJ. Moreover, the substantial evidence that NPC knew that Zometa was causing BONJ in patients such as Mrs. Baldwin and NPC's extensive efforts not only to cover up that fact so as to avoid interference with NPC's mass push to "convert" Aredia prescribers/users into Zometa prescribers/users but to prevent others from warning of the dangers of BONJ is relevant to the issue of punitive damages and NPC's evil and improper motive (i.e. to sell more Zometa). *See*, *Topper v. Midwest Div., Inc*, 306 S.W.3d 117, 132 (Mo. App. W.D. 2010) (A submissible case for punitive damages is made if ―the evidence and the inferences drawn there from are sufficient to permit a reasonable juror to conclude that the plaintiff established with convincing clarity-that is, that it was highly probable-that the defendant's conduct was outrageous because of evil motive or reckless indifference.)

I. Mrs. Baldwin's notes

While Mrs. Baldwin's notes are admissible under FRE 803(1),(2) and/or (3) or FRE 807 (residual hearsay exception where other indicia of reliability), Plaintiff does not intend to offer those notes into evidence in her case in chief. In the event, that those documents are to be used in impeachment or rebuttal, Plaintiff request that NPC's objections be addressed at that time.

II. Missouri law

NPC claims that under the Learned Intermediary Doctrine it only had a duty to

warn Dr Hueser, the prescribing doctor and therefore evidence of its lack of warnings to Dr Miller, Mrs. Baldwin's dentist, should be excluded. NPC is incorrect for a number of reasons.

First, generally, a manufacturer has a duty to adequately warn the ultimate user of any dangers that accompany a foreseeable use of its product. *Nesselrode v. Executive Beechcraft, Inc*., 707 S.W.2d 371, 382 (Mo. banc 1986). An exception to this general rule has been recognized in Missouri and elsewhere where the defendant can show that it provided an adequate warning to a "learned intermediary" with the intent that such warning be provided to the ultimate user of the product. However, NPC waived the learned intermediary defense and therefore cannot rely on that defense at the trial of this matter. *See* Plaintiff's pending Motion to Strike NPC's Learned Intermediary defense incorporated herein.

Second, the MDL Court and this Court have already recognized that NPC had a duty to warn Dr Miller in denying NPC's motion for summary judgment on that basis. *See* 10/20/2011 order denying NPC motion for summary judgment. Dkt 117 at p. 5 (". . . the MDL judge also found there was a genuine issue of material fact as to whether different warnings would have changed Dr. Miller's behavior. [Doc. # 109-1 at 9]."). That ruling is law of the case.

Finally, NPC's argument that NPC had no duty to warn dental providers as a matter of law is simply incorrect as a matter of Missouri law. In Missouri, as elsewhere, the duty to warn arises from the foreseeability of harm. *See, Lopez, Jones v. Three rivers Electric Cooperative*, 26 S.W.3d 151 (Mo. 2000), *citing, Zuber v. Clarkson Const. Co*., 251 S.W.2d 52, 55 (Mo. banc 1952)("Foreseeability for purposes of establishing whether a defendant's conduct created a duty to a plaintiff depends on whether the defendant should have foreseen a risk in a given set of circumstances. . . For purposes of determining whether a duty exists, this Court has defined foreseeability as the presence of some probability or likelihood of harm sufficiently serious that

ordinary persons would take precautions to avoid it").

Thus under Missouri law, Novartis had a duty to warn Mrs. Baldwin, the ultimate user, as well as other health care providers in a position to reduce harm: Dr Hueser and Dr Miller. It warned none of them until after Mrs. Baldwin had already had two extractions and irreversible BONJ.

NPC had many opportunities to warn Mrs. Baldwin and her doctors but simply failed to do so. For instance, the Physicians Desk Reference ("PDR") relied on by many physicians, including Dr Hueser, for prescribing information did not contain any mention of the dangers of BONJ whatsoever at anytime prior to the 2005 edition. Moreover, NPC could have, but did not, instruct its sales reps to inform Oncologists or any other health care providers of the risk of BONJ. In fact, the evidence will show that sales reps visited Dr Hueser approximately once a week - 50 plus times a year - from 2002 – September 2004 in an effort to promote the sale of Zometa. However, there is no record that any of them ever mentioned the risk of BONJ to Dr Hueser at any time before Mrs Baldwin had her 2nd tooth extracted on September 9, 2004. This is all the more shocking because NPC expressly ordered its sales reps not to share information re: BONJ with doctors and not to even raise the topic at all in an August 2003 NPC memo. Then in a classic case of a day late and a dollar short, NPC claims that it sent a "dear doctor" letter to oncologists (but not to dentists) in late September 2004 warning for the first time of the dangers of BONJ. NPC claims that it sent a similar letter to dentists in May 2005. Unfortunately for Mrs. Baldwin, the irreversible damage was already done.

The evidence will show that NPC learned from Dr. Regina Landesberg in December 2002 that one oral surgeon in New York, Dr. Sal Ruggiero, reported 26 cases of BONJ, most of which were triggered by tooth extractions. Thus, it knew no later than that date that dentists

were in a position to avoid what one oral surgeon (Dr Marx) called a growing epidemic. That NPC's duty to warn would not extend to the very professionals likely to trigger the harm is unconnected to the purposes of tort law or basic notions of duty and proximate cause long embraced in Missouri and elsewhere. In this regard, the Restatement (Third) of Torts – Product Liability merely brings product liability law firmly in line with traditional tort notions of duty and proximate cause law when it states:

> A prescription drug… is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risk of harm in accordance with the instructions or warnings.

Restatement (Third) of Torts – Products Liability § 6(d). In doing so, it simply reaffirms the notion of foreseeability that has long existed in Missouri and has been recognized previously in this litigation. *See Hogan v. Novartis Pharms. Corp*., 2011 WL 1533467, *9 (E.D.N.Y. April 24, 2011) ("…none of the cases in defendant's long list stand for the proposition that prescribing physicians are the *only* treating medical professionals who must be warned."); *Stevens v. Novartis Pharms. Corp*., 358 Mont. 474, 247 P.3d 244, 260 (2010) *cert. denied,* ____ *U.S.* ____ (June 2011). *see also* Order on Motions *In Limine*, *Fussman v. Novartis Pharms. Corp*., p. 11, No. 1:06-cv-00149 (M.D.N.C. Oct. 29, 2010) (Dkt #441) ("*Fussman* MIL Order") (allowing testimony of other healthcare providers with the jury instruction on the legal standards to apply) (not attached).

For these reasons, Plaintiff should not be excluded from introducing evidence that NPC had a duty to warn dental professionals directly.

III. NPC's Conduct or Knowledge after September 9, 2004

a. Generally: Evidence of Post-Injury, Post-Drug-Use Corporate Conduct is probative because it shows a continuing effort not to adequately warn as the evidence Plaintiff plans to introduce demonstrates. NPC argues that it did the best with the information it had. Plaintiff's evidence, even evidence that occurred after Mrs. Baldwin was diagnosed with BONJ on October 26, 2004, challenges that assertion by showing that any "missteps" in 2002-2004 were not inadvertent but a corporate plan that continued for years, until Zometa had "converted" most Oncologists in the United States from Aredia -which had gone "off patent" in the early 2001 - to Zometa - which enjoyed patent protection through 2012. Additionally, as mentioned previously, evidence of corporate conduct may be probative of general causation and specific causation regardless of its date and will show defendant's knowledge about ONJ. *See Hogan v. Novartis Pharms. Corp.,* 2011 WL 1533467, *11 (E.D.N.Y. Apr. 24, 2011) (Cogan, J.). Finally, NPC 's "bad acts" in failing to warn despite repeated recommendations to warn are relevant to the issue of punitive damages.

b. NPC's 2007 Zometa® Label Changes

In 2007, NPC took "well documented" off of its label as it relates to supposed "other well documented multiple risk factors" for ONJ. Its prior label had falsely asserted a litany of supposed "well documented multiple risk factors" for ONJ, besides bisphosphonate use. Plaintiff intends to offer the 2007 Zometa label as direct evidence that NPC's prior reference to the existence of supposed other well documented risk factors was false when made, and made with intent to divert attention away form Zometa and to sow confusion in the medical community at large in a successful attempt to sell more Zometa. This evidence is relevant to the issue of causation in that NPC will certainly try to argue that something other than Zometa/Aredia

caused Mrs. Baldwin's BONJ. The evidence is also relevant to NPC's liability for punitive damages as it supports the idea that NPC acted in a way to mislead the public and the medical community in order to protect Zometa sales.

NPC argues that its removal of the "well documented" language from its 2007 label is evidence of a "subsequent remedial measure" and should be excluded under FRE 407 (which precludes evidence of a subsequent label change to show "a [prior] need for a warning or instruction"). It is nothing of the kind. The commentary to FRE 407 explains the rationale behind the rule:

> the rule rejects the notion that "because the world gets wiser as it gets older, therefore it was foolish before." *Hart v. Lancashire & Yorkshire Ry. Co*., 21 L.T.R. N.S. 261, 263 (1869). Under a liberal theory of relevancy this ground alone would not support exclusion as the inference is still a possible one. (2) The other, and more impressive, ground for exclusion rests on a social policy of encouraging people to take, or at least not discouraging them from taking, steps in furtherance of added safety. The courts have applied this principle to exclude evidence of subsequent repairs, installation of safety devices, changes in company rules, and discharge of employees, and the language of the present rules is broad enough to encompass all of them. See Falknor, Extrinsic Policies Affecting Admissibility, 10 Rutgers L.Rev. 574, 590 (1956).

NPC's 2007 removal of false information concerning non existent "other well documented multiple risk factors" is not an example of NPC "getting wiser as it gets older therefore it was foolish before". It is exactly the opposite. It is evidence that NPC either lost the "well documented" evidence of other causes that it claimed were known to science in 2003 – 2006 – a highly unlikely possibility - or that NPC was not being truthful in the first instance by asserting the existence of "other well documented multiple risk factors" for BONJ in 2003 – 2006. In fact, this is confirmed by NPC's own Epidemiologist, Dr. Sablinska, who when asked about a proposed Zometa label change on June 14, 2005, takes issue with NPC's insertion of the phrase "well documented" saying "There is really very little well documented knowledge

concerning ONJ". Plaintiff Trial Exhibit 578. Apparently, unbeknownst to Dr Sablinska, the claim of multiple other "well documented" causes of BONJ was already on the Zometa label. In short, NPC would have this court believe that time moved backwards and that "well documented" scientific evidence of "multiple" other causes of ONJ that supposedly existed in December 2003 (when the 9/03 NPC label change for Zometa first went into circulation) were somehow lost to science by 2007. This is nonsense.

Likewise, the social policy which encourages people to "take, or at least not discourage them from taking steps in furtherance of added safety" cannot be so broad as to protect the removal of blatant falsehoods from drug labels years later (as opposed to the subsequent fixing of potholes and other dangerous conditions or the addition of needed warnings or instructions which FRE 407 clearly intends to protect). NPC would have this court believe that Zometa's need for a warning or instruction lessened over time. Even if this is true, FRE 407 only precludes evidence of "a need for a warning or instruction" not the subsequent removal of false statements from prior warnings.

In the alternative, Plaintiff requests that the Court allow Plaintiff to reserve the right to use the 2007 label changes to impeach certain of NPC's witness testimony if it is necessary, as expressly allowed under FRE 407. At trial, Novartis will likely "open the door" to the post 2007 label in a whole host of ways. For instance, in other cases NPC has argued that 'the drug is still prescribed' and attempts to argue that nothing has changed. If Novartis makes such an argument, it will have opened the door to what the package insert now says.

IV. Certain Corporate Conduct/Documents Before the September 2003

First, NPC misleadingly labels September 2003 as the Notice "Cut-Off Date". It is nothing of the sort. All of the documents NPC seeks to exclude identified as "corporate documents" are admissions by NPC by their employees or agents. *See* Fed. R. Evid. 801(d)(2). Evidence of corporate conduct may be probative of general causation regardless of its date and may show Defendant's knowledge about ONJ. *See Hogan v. Novartis Pharms. Corp.*, 2011 WL 1533467, *11 (E.D.N.Y. April 24, 2011) (Cogan, J.). At the very least NPC's objections to these documents are premature. In the event this Court does not simply rule that all evidence of what NPC should knew or should have known prior to September 2003 is relevant to whether it had a duty to warn after that date, Plaintiff requests that this Court reserve judgment on all "corporate conduct" documents NPC seeks to exclude until placed in context at time of trial. *Stevens v. NovartisPharms. Corp*., Opinion and Order on NPC's Motion in Limine to Exclude Evidence and Testimony on Irrelevant and Inadmissible Corporate Actions and Knowledge, p. 3, Dept. 3 Cause No. DV-08-100 (Mont. 4th Dist., Missoula Cty., Oct. 13, 2009) (attached as Exhibit 1). In any event, all such documents dated before September 2003 that relate to whether NPC knew or should have known that bisphosphonates in general, and Zometa/Aredia in particular can cause bisphosphonate induced ONJ are relevant to any potential warnings she or her physicians should have received and are therefore admissible. When confronted with this very issue, Judge Beaty in North Carolina concluded generally that documents prior to the point of Plaintiff's diagnosis are relevant to show NPC's knowledge and the reasonableness of the warnings. Order on Motions *In Limine*, *Fussman v. Novartis Pharms. Corp*., p. 13, No. 1:06-cv-00149 (M.D.N.C. Oct. 29, 2010)(Dkt #441) ("*Fussman* MIL Order") (previously provided to the Court). Included in the universe of knowledge that NPC knew or should have known as an expert in the field are

the Gotcher and Jee, and Stark articles that demonstrated as far back as the 1980s that the jaw bones of rats given "di-phosphonates – the old name for bisphosphonates – became "devitalized" (ie dead). NPC witness Green acknowledges having these articles in his possession as far back as 1986.

Likewise, Plaintiff can present evidence that both Dr. Marx and Dr. Ruggiero thought about Phossy Jaw in their analysis of the cause of ONJ in their patients on bisphosphonates because the problem appeared similar. Plaintiff should not be excluded from introducing evidence that informed certain witnesses on causation.

Finally, as an expert in the field NPC knew or should have known of the multiple cases of BONJ that was unequivocally present in clinical trials going back to the 1990. The fact that NPC claims to not have uncovered them until 2005 is yet more evidence of negligence. The jury will be free to determine the credibility of NPC's story. This is especially true where the evidence of BONJ in the clinical trials was independently substantiated by multiple reports of BONJ to the FDA and NPC on the AERS and Medwatch reporting system – prior to the December 2002 when NPC claims to have first heard of BONJ. The jury should be allowed to weigh this evidence on the issues of negligence, causation and punitive damages.

V. Certain Aspects of Dr. Marx's Testimony
a. Concerning His Experience with ONJ Patients

All of the courts Dr. Marx has testified before have rightfully concluded that the number and type of cases Dr. Marx has treated is relevant to his qualifications and the foundation for his opinions. *See Fussman* MIL Order at p. 13; *Hogan*, 2011 WL 1533467, at *11; *Stevens v. Novartis*, Case No. DV-08-100 (Mont. 4th Dist. Missoula Cty., October 14, 2009) Trial Tr. at 547-48 (not attached). Such evidence is properly before the jury in this case as well.

VI. Evidence Concerning Adverse Drug Experience ("ADE") Reports

ADE reports are relevant to show notice to Defendant regardless of when they were filed. Alleged "dissimilarities to Plaintiff's case affect the weight rather than the admissibility of this evidence. *See Fussman* MIL Order at p. 12 (allowing ADE reports submitted during pre-notice period with limiting instruction to only be considered for notice to Defendant) (Ex. 2). *See also Hogan*, 2011 WL 1533467, at *13. Also, the ADE reports are part of Defendant's expert causation opinions. The Deutsch Court ruled that ADE reports are useful to expert opinion and can be used Memorandum of Decision and Order, *Deutsch v. Novartis Pharms. Corp.*, 2:09-cv-04677-ADSWDW, at p. 52-53 (E.D.N.Y. Mar. 8, 2011) (Doc. 438).

VII. Certain Specific NPC documents

a. May 5, 2003 e-mail from NPC Employee Stefano Fratarcangeli (ZAED-00079439-43)

The fact that Dr. Ruggiero was Mrs.. Baldwin's treating oral surgeon does not make this document prejudicial to NPC. In fact, it makes the document that much more relevant because of Dr. Ruggiero's direct involvement in Mrs.. Baldwin's treatment. Judge Cogan allowed the admittance of this e-mail as evidence because "the letter could be argued to show defendant's knowledge about ONJ at a crucial juncture" in Plaintiff Hogan's treatment. *Hogan*, 2011 WL 1533467, at *12. This time period is no less crucial in Mrs.. Baldwin's chronology. NPC fails to cite to a case where this e-mail has been excluded because not a single court has ever excluded this e-mail in any of the four cases tried thus far.

b. June 20, 2003 e-mail from Goessl (ZAEM-00133003-04); and

c. July 10, 2003 e-mail from Goessl (ZAEM-00077111)

These two e-mails from Dr. Carsten Goessl, at the time the Senior Clinical Research Physician for NPC, are clearly admissions by NPC by one of their employees and/or agents. The

e-mails are highly probative of Defendant's knowledge about ONJ, again during a crucial period when a warning was particularly important. *See Hogan* MIL Order at p. 21-22. Again, NPC fails to cite to a case where these e-mails were excluded because they have always been introduced as evidence to the jury in every Aredia® and Zometa® case every tried.

d. December 1, 2003 e-mail from Linguri and Attached Agenda for Upcoming Osteonecrosis Advisory Board (ZAEM-01199529-32)

This e-mail from Linguri attaching a draft agenda for NPC's initial Advisory Board may have been sent close to the time that Mrs.. Baldwin received her last treatment but it demonstrates NPC's intent and motive leading up to the Advisory Board and NPC's intent to avoid properly warning about ONJ. Moreover, it demonstrates that NPC had no intention of warning at any time but only to implicate other factors in the disease its drugs caused. This document also addresses causation which should be relevant regardless of the date of the e-mail.

e. January 18, 2004 Letter from Klein (ZA-0525027)

Despite the date on this letter it is a response to a Novartis Emergency Management ("NEM") team request. The NEM team assembled to address ONJ in Aredia® and Zometa® patients was established long before December of 2003. Samuel Klein is a sales representative working for and representing Novartis. The document contains writing on it by Debbie Dunsire, the head of the NEM team. The key observation in this e-mail is that neither senders nor recipients, all Novartis employees rebukes the "enemies and allies" statement. This is probative of NPC's attitude towards issuing true and correct warnings. The fact that this interaction between the high level Dunsire and the sales person Klein contains no rebuke or correction of attitude is particularly relevant as to NPC's intent at the high levels. This is particularly true when read in connection with the May 5, 2003 e-mail from Stefano Fratarcangeli (ZAED-00079439-43) offers to set about avoiding that Dr. Salvatorie Ruggiero's reports of ONJ in

Aredia® and Zometa® patients is ever published ("Fratarcangeli e-mail") It also provides evidence of the attitude of the sales force who directly communicated with physicians.

f. March 12, 2004 e-mail from NPC's Former Employee, Linda Weiss (ZAEM-00824590)

This e-mail addresses two competing arguments as to the intent and motive of negotiations for the September 2003 label, specifically the "risk factors" language. NPC claims that they were negotiating for an accurate label. Plaintiff argues that they were attempting to confuse and divert attention from the truth about ONJ. NPC seeks to exclude this document because it undermines their version of the facts and strengthens Plaintiff's version, making it particularly probative. NPC is accountable for the actions of its agents as Weiss clearly was in this e-mail. This e-mail is particularly probative when viewed in context with the Fratarcangeli e-mail. Moreover it goes to cause. It describes a retrospective review of BONJ cases known to Novartis up to that time.

g. May 12, 2004 e-mail from Schubert (ZAEM-00860680-81)

h. May 12, 2004 e-mail from Ana Hoff (ZAEM-00860748-49)

i. May 28, 2004 e-mail from Schubert (ZAEM-00217697-700)

These documents are corporate documents from the very team of NPC employees that were assigned the task of addressing the ONJ problem. Dr. Schubert is no stranger to NPC and in the capacity of these e-mails is clearly serving as an advisor to the company. These e-mails go directly to the "risk factors" issue being pushed by Novartis, not its outside advisors. These emails are particularly probative when viewed in context with the Fratarcangeli e-mail. The Advisory Boards, NPC argues, were created to obtain and then disseminate accurate evidence concerning BONJ. These e-mails demonstrate that NPC rejected any information uncongenial to it. The choice to reject this information and press other material is not presented for the truth of

the matter but a pattern and habit of NPC regarding BONJ. Further, the Ad Board originally met in December 5, 2003 and much of the material encompasses what the advisors were telling NPC then.

j. January 31, 2005 e-mail from Petraglia (ZAEM-01790080-82)

Plaintiff does not intend to introduce this email in her case in chief at trial.

k. June 15, 2005 e-mail from Sablinska (ZAEM-02131140-44)

The e-mail exchange between Dr. Katarzyna Sablinska and Mr. Geoffrey Cook, NPC Director of U.S. Public Relations, is highly probative because it shows that the perspective of the public and published literature on the topic of ONJ in bisphosphonate patients from the view point of NPC's only epidemiologist. The document goes to causation and the falsity of NPC's public information in the Fall of 2003 regarding the label. This evidence also directly addresses NPC's intent to warn at a crucial time in Plaintiff's chronology of events. The jury is entitled to evaluate this e-mail and apply it to their determination of NPC's intent and motive as the language here goes directly to NPC's alleged label misrepresentations. If the other "risk factors" were not "well-documented" in 2005 how less were they documented in 2003?

VIII Statements in Mrs Baldwin's medical records

Any statements contained in Mrs Baldwin's medical records that are relevant to her condition, diagnosis including the cause thereof, prognosis and other medical treatment for BONJ should come into evidence under the FRE 803 (4) as a statement made for medical diagnosis or treatment.

IX. Alternative Dosing

a. Alternative dosing

Evidence that NPC sought to avoid attempts to reduce the amount or duration of Zometa

treatment is relevant to negligence, causation and especially punitive damages because it demonstrates NPC's successful plan to put profits ahead of patient safety. Moreover, the potency of Aredia® and Zometa® is highly relevant. The evidence will show that Zometa® is more potent than Aredia® and that patients receiving Zometa® after Aredia®, or instead of Aredia® get ONJ faster. For this very reason, evidence regarding the potency of various bisphosphonates should not be excluded. The jury should be permitted to evaluate the evidence.

b. January 29, 2003 e-mail from NPC Employee David Epstein, (NJZAEM-00047909-47)

The January 29, 2003 e-mail from NPC employee David Epstein discusses a Japanese study involving dosing regimens for using zoledronic acid (Zometa®). This document makes more likely that the dosing regimen for Zometa® was not chosen for efficacy but as part of a corporate plan involving both benign indications and allowing larger and more frequent dosing in the oncologic indications. Mr. Epstein himself related how the dosing in the trial relates to the revenues of Zometa®. Because key issues in this case are dosing and potency, an e-mail by the CEO of the company discussing these very issues in relation to profits is highly probative and relevant. NPC's defense is that everything it did was scientifically based. This document demonstrates that when scientific inquiry might lead to results NPC did not want, that science was halted.

X. Omnibus motion

A. Out of Court Statements by Members of a panel of Physicians and oral surgeons who provided comments re: NPC's draft white paper

NPC solicited comments on a "white paper" on the problem of BONJ in patients using Zometa and Aredia. Those comments are relevant to the issue of notice (ie what did NPC know and

when did they know it). They also overcome hearsay objections, as the Court found in the *Kyle* case, when Dr Tarasoff, the head of NPC's medical affairs department, underlined certain portions of the comments and circulated them internally to other NPC employees. Dr Tarasoff's underlined comments are evidence of Dr Tarasoff's intent to communicate certain information to other NPC employees, regardless of the origin of such comments. FRE 801 (d)(2) (admission of party opponent) and/or FRE 803 (1)(present sense impression) and/or FRE 807 (general indicia of reliability).

B. Testimony from Dr. Noopur Raje, Including a Videotaped Presentation that Dr. Raje Gave in September 2005 at the AAOMS Meeting

Plaintiff requests reserving any arguments against NPC's objections to this testimony until such time Plaintiff chooses to present this evidence in its case in chief.

C. Recommendations From The Osteonecrosis Of The Jaw (ONJ) Advisory Panel, March 16, 2005

This was excluded from in the *Hogan* case, but this ruling should be considered in the context of Judge Cogan excluding any information involving the FDA. *Hogan*, 2011 WL 1533467, at *22. The Court has not made the same exclusion here. The date of the March 2005 ONJ Advisory Panel Recommendations should not matter because it is a document that also addresses causation. Therefore, it is relevant in this action. It also confirms recommendations that NPC was receiving from experts in 2003: i.e. the need to avoid dental extractions while on Zometa.

D. Hearsay Statement Made By Dr. Jack Gotcher at the Annual AAOMS Meeting in September 2005

Plaintiff requests the Court allow it to reserve the right to use this document for

impeachment purposes against NPC's witnesses. This statement is relevant because what happened at the meeting Dr. Gotcher attended is important for the jury, particularly because it demonstrates NPC had knowledge or reason to know that Dr. Gotcher did not agree with NPC's view of his own article from the 1980s that showed that bisphosphonates (at the time called diphosphonates) killed the jawbone in rice rats. Plaintiff does not intend to introduce it in its case in chief. See generally definition of bisphosphonates in Wikipedia: http://en.wikipedia.org/wiki/Bisphosphonate ("**Bisphosphonates** (also called **diphosphonates**) are a class of drugs that prevent the loss of bone mass, used to treat osteoporosis and similar diseases.")

E. Sales and Marketing Materials

NPC seeks to exclude evidence of sales and marketing materials provided by NPC's sales reps to Dr Hueser, including a patient pamphlet given to Dr Hueser in late September 2004, two weeks after Dr Miller extracted Mrs Baldwin's 2nd tooth. The reason is simple. The materials place NPC is a bad light in that it shows that NPC was more interested in projecting a healthy life affirming image of Zometa in an effort to increases sales of the drug but makes no makes no mention of BONJ until September of 2004.

Judge Beaty considered this information relevant to the trial in North Carolina because the materials were part of the general information provided to the medical community. *Fussman* MIL Order at p. 7-8. Contrary to NPC's objection to sales and marketing information, this evidence is particularly relevant to NPC's motives. The jury should be able to compare these materials and the materials generally available to the public to what NPC was telling doctors in learned journals. This comparison is probative of efforts to warn the community at large and is thus relevant to punitive damages.

The pamphlets are also relevant to the issue of causation because, for instance, the September 2004 pamphlet, ZAEM-001425069 – 072 discusses osteonecrosis of the jaw as a "serious condition" that can be made worse by surgery "because it may make the condition worse". The pamphlet also recommends that patients "provide [their] dentist and [their] oncologist with each other's name and telephone number for consultation". Finally, the pamphlet makes the same spurious claims that "it is not known what role, if any, [bisphosphonates] play in [ONJ's] development" while aiming to spread the possible blame to . other possible causes such as alcohol, cigarettes, anemia, poor nutrition, poor blood circulation, and poor dental health. *Id*. The jury should be allowed to review these deliberate falsehoods and see them for what they were – a deliberate attempt to divert attention away from Zometa so that NPC could sell more Zometa. This evidence goes directly to NPC's intent to warn at a crucial time in Plaintiff's chronology of events. The jury is entitled to evaluate NPC's intent to warn as the language at issue here goes directly to NPC's alleged delay and misrepresentations.

Finally, direct to consumer advertising is relevant because it provides an exception to the learned intermediary defense (ie where direct to consumer advertising occurs, drug manufacturers cannot discharge their duty to warn the consumer by providing an adequate warning to a learned intermediary).

F. Testimony Or Argument Regarding Alleged Fraud On The FDA Or Alleged Violations Of FDA Regulations

It is ultimately the drug manufacturer's responsibility to maintain a safe product and provide proper safety information in its label. *Wyeth v. Levine*, 129 S. Ct. 1187, 1198 (2009). As such, Plaintiff should not be prohibited from alleging that NPC's behavior violated certain FDA regulations or practices.

G. Miscellaneous

1. References To Articles Purporting To Be Authored By Independent Physicians But Allegedly "Ghostwritten" By Drug Companies

Plaintiff will not be introducing any evidence on the topic of Ghostwriting

2. Testimony Concerning Foreign Regulatory Actions And Materials

Plaintiff's main point regarding foreign regulatory actions and materials is to demonstrate NPC's response and knowledge world wide to the reports of ONJ in bisphosphonate patients. NPC had information on patients all over the world to inform its decision on how to move forward with the reports of ONJ in the United States and Plaintiff should be permitted to present this information to the jury. Plaintiff does not plan to introduce evidence of what foreign regulatory agencies actually did other than request or receive information from NPC. NPC is a corporation that receives knowledge and information on its drug from all over the world. It should not be able to artificially cabin off that information simply because it has an arm in the U.S. regulated by FDA.

3. Discovery Disputes

If relevant, such evidence should be admitted. For instance, if NPC fails to provide certain information in discovery, such as the names and addresses of the doctors to whom it supposedly sent the Dear doctor letters in September 2004 and May 2005, and then attempt to introduce such evidence through a NPC witness – assuming the court does not sustain Plaintiffs objection to the admission of such evidence - Plaintiff should be entitled to cross the examination the witness on the fact the list was never produced in discovery. Otherwise, Plaintiff requests that the Court address any such issues as they arise during trial.

4. Characterization of Counsel

Plaintiff request that this Court address any such issue or objections during the normal course of trial.

5. Incestous relationship

This Court has sufficient tools at its disposal to handle any such objections that may arise during the course of trial without providing a list of words that cannot be used by either side.

6. Dr Parisian is the former chief medical officer of the FDA

This motion is a frivolous waste of time

7. Reference to dental pain

Plaintiff is allowed to ask jurors to draw from their own personal experiences in weighing Mrs Baldwin's pain and suffering. Thus this objection should be overruled.

8. Evidence re: moral obligations and legal conclusions

This Court has sufficient tools to weigh any such objections as they may arise during the course of the trial. Plaintiff requests that this Court address any such objections at that time.

9. Issues re: Drugs other than Zometa and Aredia

All of the information NPC seeks to exclude regarding other bisphosphonates goes to Plaintiff's argument that there is a class effect to the ONJ injury. The evidence of a class effect goes to the argument that NPC knew or should have known sooner that ONJ was a potential side effect - and adequately warned of that risk. The evidence also goes to whether Zometa/Aredia were unreasonably dangerous by failing to warn of the risk of BONJ, causation, and punitive damages.

a. Evidence Concerning the Alleged Propensity for Oral Bisphosphonates Made by Other Manufacturers to Cause ONJ

It is difficult for the jury to understand what NPC should have known and when without

presenting them with evidence of ONJ in patients taking other bisphosphonates. Dr. Ruggiero and Dr. Marx both treat patients for ONJ that are taking other bisphosphonates and these other patients weigh into their opinion on causation. Further, the fact that bisphosphonates given to non-cancer patients cause ONJ completely undermines NPC's argument that the other "concomitant risk factors", such as cancer, cause it. Furthermore, the evidence that NPC knew that bisphosphonates cause ONJ in non cancer patients, supports Plaintiff's claim for punitive damages.

b. Evidence Regarding Reclast

Reclast is simply zoledronic acid (Zometa®) in a different package and with a different dosing schedule. The evidence is clear that NPC, in every bit of information it gave to the FDA or the medical community, had one eye on the "benign" indication for zoledronic acid that is osteoperosis. One reason NPC would not adequately warn Zometa® users was it wanted an approved indication for osteoperosis for Reclast. As soon as Reclast was approved by the FDA, NPC took the "well documented" alternate risk factors off the Zometa® label. NPC's motive surrounding the approval zoledronic acid for a different indication at the same time Zometa® is experiencing reports of ONJ are highly relevant to NPC's intent to mislead patients long enough to get Reclast approved.

In addition, Plaintiff should be permitted to present evidence regarding regulatory enforcement or interactions between FDA and NPC concerning other drugs for the purposes punitive damages.

10. Compensation to Dr Marx

The amount of compensation paid or not paid to an expert witness is relevant to that witnesses' credibility. Therefore, the jury should be allowed to consider such evidence if offered in direct or as impeachment evidence.

11. Reference To NPC's Corporate Structure Or To The Fact That NPC's Parent Company Is Based In Switzerland

How and where NPC makes the decision that affect patients on their drugs, such as Mrs. Baldwin matters. Many witnesses, including David Epstein the CEO, discuss the location of their offices or decision making processes and NPC presents no valid argument for why this information should be excluded. The fact that NPC is a global organization and can gather information from all over the world is important information for the jury. Further, a mere assertion of prejudice toward the Swiss on the part of Missouri jurors unsubstantiated by any fact or history, ought not be adopted by the Court.

12. Other Litigation Involving Bisphosphonates

This evidence will invariably come into evidence during cross examination of expert and live witnesses who have testified previously in this mdl. Moreover, Dr Marx will testify regarding the many other patients he has treated with BONJ. The jury should be allowed to consider and weigh this testimony.

IV. CONCLUSION

For all these reasons, Plaintiffs request that the foregoing motion be denied as set forth above.

Respectfully submitted,

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Dated: February 27, 2012

CERTIFICATE OF SERVICE

I herby certify that a true and correct copy of the foregoing PLAINTIFF'S SUGGESTION was furnished by operation of the Court's Electronic Case Filing System on counsel of record in Case No 2:06:04049-CV-NKL on this 27th day of February, 2012.

/s/ John J. Beins
John J. Beins, Esq.